

US EPA ARCHIVE DOCUMENT

DATE OUT: 30/JUN/1999

PRODUCT CHEMISTRY REVIEW OF: TGAI [X] MANUFACTURING-USE [X] END-USE
PRODUCT [] BARCODE No.: D255489 EPA RECEIVED DATE: 29/OCT/1998 REG./File Symbol
No.: 3125-270 NAME: Sencor Technical, 94% Metribuzin ACTION CODE: 674 COMPANY NAME:
Bayer Corp. MRID NO: 147003, 161509, 412844-01, 428902-01, 156324, 416964-01, 425982-03,
161507, 428902-02, and 424256-01

FROM: Ann Hanger, Environmental Protection Specialist *A. Hanger*
Product Reregistration Branch/SRRD (7508C) *OK, J. M. M. 6/30/99*

TO: Cynthia Williams, CRM
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INTRODUCTION:

The applicant, Bayer Corporation, submitted product chemistry data, a label EPA received 29/OCT/1998, and a basic formulation CSF dated 29/JUL/1993, seeking FIFRA Section 4 reregistration of the end-use product, EPA Reg. No. 3125-270.

FINDINGS:

1. A Reregistration Eligibility Document (RED), case #0181, for Metribuzin was issued during February 1998. According to the Metribuzin RED, there are two data gaps, certification of limits (GRN 830-1750) and enforcement analytical method (830-1800). These data gaps must be addressed in connection with the RED. However, the remaining generic database supporting the reregistration of metribuzin has been determined to be substantially complete.
2. The applicant should be advised to submit or reference product chemistry data requirement 830.6313 pertaining to product stability identified in this submission as a data gap since the submitted studies using a formulated product is unacceptable.
3. An adequate analytical method is available for enforcement. The method, Miles Central Analytical Method C-28.01, included in MRIDs. #428902-02 & 147003, is entitled, "GLC Determination of Sencor and Bay 98719" and "Accuracy Study for Miles Central Analytical Method C-28.01 for Sencor." The method is applicable for the determination of the true concentration for Sencor. In this method, Sencor was determined gravimetricly using high purity standards.
- 4a. The label ingredient statement complies with the requirements of 40 CFR §156.10(g) and PR Notice 91-2. The storage & disposal statements comply with the requirements of 40 CFR §156.10(i)(2)(ix) and PR Notices 83-3 and 84-5. No physical or chemical hazards are anticipated for this product.
- 4b. The applicant should be advised to comply with PR Notice 97-6 by claiming on the product's label, "Other Ingredients" instead of "Inert Ingredients" since impurities in a TGAI are not inerts.

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- 5a. The submitted Confidential Statement of Formula (CSF), a basic formulation dated 29/JUL/1993, is unacceptable because the nominal concentration of the active ingredient does not agree with the label claim nominal concentration as per the regulations of PR Notice 91-2. For consistency with the label claim nominal concentration, the applicant should be advised to correct the percent nominal concentration in Column 13(b) from 94.4% to 94.0%. Method recovery $\geq 98\%$ for a TGAI will be acceptable as per the regulations of 49(207)FR 42863, 24/OCT/1984.
- 5b. The upper and lower certified limits of the active ingredient must be within the standard limits of 40 CFR §158.175(2).
- 5c. All ingredients claimed on the CSF are cleared for use in pesticide formulations.

CONCLUSIONS:

With the exception of findings 2, 4b, 5a, and 5b, the registrant has satisfied the product chemistry data requirements for the reregistration of EPA Reg. No. 3125-270. Upon review of the stability data (830-6313) submitted for the subject product, revision of "Inert Ingredients" to "Other Ingredients" on the label as indicated in finding 4b, and correction of the CSF as indicated in findings 5a and 5b, the product chemistry data requirements for reregistration of 3125-270 will be complete.

DETAILED CONSIDERATIONS

REVIEW OF PRODUCT CHEMISTRY DATA:

1. A statement of data confidentiality dated 24/AUG/1989 was included with this submission claiming confidentiality of the data requirements on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C). Review of CBI information is to be found in Confidential Appendix A.
2. A GLP statement dated 24/AUG/1989 was included with this submission to the effect that the submitted studies were not conducted in compliance with GLP requirements of 40CFR §160.135(b).

DATA SUBMITTED

MRID #147003 The submitted study entitled, "Product Chemistry of Sencor Technical," was authored by various authors, performed by Mobay Chemical Corporation, completed 19/APR/1985, 104 pages.

MRID #161509 The submitted study entitled, "Maximum and Minimum Certified Limits for Technical Sencor," was authored by T. D. Talbott, performed by Mobay Corp., completed 27/DEC/1983, 4 pages.

MRID #412844-01 The submitted study entitled, "Product Chemistry of Sencor Technical," was authored by T. D. Talbott, performed by Mobay Corp., completed 16/AUG/1989, 86 pages.

MRID #428902-01 The submitted study entitled, "Product Chemistry of Sencor Technical," was authored by L. D. Fontaine, performed by Miles Inc., completed 09/AUG/1993, 7 pages.

MRID #156324 The submitted study entitled, "Product Chemistry of Sencor Technical," was authored by unknown, performed by Mobay Chemical Corp., completed 19/APR/1985, 127 pages.

MRID #161507 The submitted study entitled, "Volatile and Nonvolatile N-Nitrosamine Analyses in Sencor Technical and Sencor 50 Wettable Powder Under Storage Conditions" was authored by T. D. Talbott and K. Riegner, performed by Mobay Corp., completed 16/JUN/1986, 106 pages.

MRID #428902-02 The submitted study entitled, "Product Chemistry of Sencor Technical," was authored by L. D. Fontaine, performed by Miles, Inc., completed 9/AUG/1993, 7 + 22 pages.

MRID #424256-01 The submitted study entitled, "Supplemental Product Chemistry of Sencor Technical," was authored by L. D. Fontaine, performed by Miles, Inc., completed 01/MAY/1992, 11 pages.

Group A, Series 830-Product Identity, Composition, and Analysis (40 CFR 155, 160, 162, 167, 175 & 180)

830-1550 Product Identity and Composition

The identity of all ingredients in this product are listed on the product's CSF, a basic formulation dated 29/JUL/1993.

830-1600 Description of Materials Used to Produce the Product:
Refer to Confidential Appendix A.

830-1650 Description of Formulation Process:
Refer to Confidential Appendix A.

830-1670 Discussion of Formation of Impurities:
Refer to Confidential Appendix A.

830-1700 Preliminary Analysis:
Refer to Confidential Appendix A.

830-1750 Certified Limits:
Refer to Confidential Appendix A.

830-1800 Enforcement Analytical Method MRID #428902-02 & 147003:

The true concentration for Sencor was determined gravimetricly using high purity standards. The Sencor content was then measured in each using Miles Central Analytical Method C-28.01. The

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percent active ingredient content for Sencor was determined using: mean (R) of the ratios of peak areas of the Sencor primary standard (S) and the internal standard di-n-butyl phthalate (I); The ratios of peak areas of the Sencor analyte (A) and the internal standard di-n-butyl phthalate (B); The weight of the Sencor primary standard (W') and the percentage purity (P) and the weight of the Sencor analyte (W). The AI analysis was replicated three times.

For each AI determination, the standard was prepared by weighing $0.10-0.12 \pm 0.0001$ g of Sencor primary standard in a 50 mL volumetric flask. Five mL of internal standard, 1% (v/v) di-n-butyl phthalate in dichloromethane was pipetted into the flask. For each AI determination, the synthetic sample was prepared by weighing $0.93-0.94 \pm 0.0001$ g of Sencor primary standard, $0.01-0.02 \pm 0.00001$ g of Butylthion, $0.01-0.05 \pm 0.00001$ g of Sencor Methyl Amine (SMA), and $0.04-0.05 \pm 0.00001$ g of Sencor N-Methyl Isomer (NMI) into a 500 mL volumetric flask. Fifty mL of internal standard, 1% (v/v) di-n-butyl phthalate in dichloromethane was pipetted into each flask. All flasks were diluted to volume with dichloromethane and the solutions were shaken to mix them thoroughly. An aliquot of each was then placed into a glass sample vial and loaded into an autosampler. Separate 1 μ L injections of each solution were made on a 5 m x 0.53 mm, 1.0 μ L film thickness, J & W Scientific DB-225 column.

Group B, Series 830-Physical and Chemical Properties (40 CFR 158.190): MRID No: 147003

GUIDELINE REFERENCE NO.(GRN)/TITLE	VALUE OR QUALITATIVE DESCRIPTION/METHOD(s) USED WHERE APPLICABLE AND REFERENCES
-6302 Color	White
-6303 Physical State	Solid crystalline
-6304 Odor	Characteristic, slight musty
-6313 Stability to normal and elevated temperatures, metals, and metal ions	Data gap
-6314 Oxidation/Reduction: Incompatibility	NA
-6315 Flammability/Flame Extension	NA
-6316 Explodability	No impact explosive characteristics
-6317 Storage Stability	Very good chemical stability with a shelf life projected to 2 years.
-6319 Miscibility	NA-product is not a liquid.
-6320 Corrosion Characteristics	Not corrosive.
-6321 Dielectric Breakdown Voltage	NA-product is not an end use product.

-7000 pH	5.5 (1% slurry)
-7100 Viscosity	NA-product is not a liquid
-7200 Melting Point	126.2°C
-7220 Boiling Point	NA-TGAI is a solid at room temperature.
-7300 Density/Relative Density Bulk Density	1.2 g/mL at 20°C
-7370 Dissociation Constant in Water	1.0 ± 0.1
-7550 Octanol/Water Partition Coefficient	44.9 at 20°C
-7840 Water Solubility	1.2 g/L (at 20°C); in hexane 1 g/L; dichloromethane 319 g/L (from MRID 424256-01), toluene 87 g/L, 2-propanol 77 g/L.
-7950 Vapor Pressure	5.7 E-07 mbar at 20°C (PAI)

Page ____ is not included in this copy.

Pages 6 through 7 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☒ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☐ A draft product label.
- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☐ FIFRA registration data.
- ☐ The document is a duplicate of page(s) _____.
- ☐ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
